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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/821,939	04/12/2004	Tae H. Ji	028750-229	2139

21839 7590 06/29/2006

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EXAMINER	
BORGEEST, CHRISTINA M	
ART UNIT	**PAPER NUMBER**
1649	

DATE MAILED: 06/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/821,939	JI ET AL.	
	Examiner	Art Unit	
	Christina Borgeest	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17 and 19-53* is/are pending in the application.

4a) Of the above claim(s) *1-15 and 19-53* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/8/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Response to Amendment

Formal Matters

The amendment filed 27 April 2006 is acknowledged. Claims 1-63 are pending. Claims 1-15 and 19-53 are withdrawn as directed to non-elected subject matter. Claim 18 is cancelled. Claim 16 is amended. Claims 16 and 17 are currently under consideration.

Objections/Rejections Withdrawn

Specification

The objection to the specification as set forth at p. 6 of the prior office action (mailed 27 October 2005) for minor informalities is withdrawn in response to Applicants' corrections.

Claim Objections

The objection to claims 16 and 17 under 112, as set forth at p. 7 of the prior office action (mailed 27 October 2005) for claiming subject matter outside the scope of the elected invention has been withdrawn in response to Applicants' amendment to include the limitation "female" subject.

Claim Rejections - 35 USC § 112

The rejection of claim 18 under 112, first paragraph as set forth at p. 7 of the prior office action (mailed 27 October 2005) for failing to comply with the enablement requirement has been withdrawn in response to Applicants' cancellation of that claim.

In addition, the rejection of claim 18 under 112, first paragraph as set forth at p. 10 of the prior office action (mailed 27 October 2005) for failing to comply with the written description requirement has been withdrawn in response to Applicants' cancellation of that claim.

Claim Rejections - 35 USC § 102

The rejection of claim 18 under 35 U.S.C. 102(b), as set forth at p. 12 of the prior office action (mailed 27 October 2005) for being anticipated by Talwar et al. (cited in previous office action) has been withdrawn in response to Applicants' cancellation of that claim.

Rejections Maintained

Claim Rejections - 35 USC § 112

The rejection of claims 16-17 under 35 U.S.C. 112, first paragraph, as set forth at pps. 7-10 for failing to comply with the enablement requirement is withdrawn in part in response to Applicants' amendment of the claims to recite "reducing the incidence of

pregnancy..." However, there is still the remaining issue of the phrase "agent". Claims 16 and 17 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of reducing the incidence of pregnancy in a female subject comprising administering to a female subject an amount of an agent effective at reducing the incidence of conception, wherein the agent inhibits CG activity or CG interaction with exoloop 1, exoloop 2 or exoloop 3 domain of the LHR, wherein the agent is CG, does not reasonably provide enablement for a method of reducing the incidence of pregnancy in a female subject comprising administering to a female subject an amount of an agent effective at reducing the incidence of conception, wherein the agent inhibits CG activity or CG interaction with exoloop 1, exoloop 2 or exoloop 3 domain of the LHR, wherein the agent is ***a biologically active fragment of CG or other synthetic or natural compound.*** The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Applicants argue at p. 16 of their remarks that the references submitted (the list on p. 16) describe assays where fragments of CG, LH receptor, other hormones and receptors were tested for their capacity to bind to the receptors, activate receptors and suppress receptors. Applicants arguments have been fully considered but are not persuasive for the following reasons. While the references submitted by Applicant do indeed describe hormone binding regions of LH/CG receptors (though not all teach the same binding region recited in Applicants' claims) as well as assays for binding and peptide synthesis; only the Leng et al. discuss the possibility of D-amino acid

substitutions in the common alpha subunit of gonadotropins at residues 32-46 in the development of potential antagonists for the control of fertility. The preponderance of the evidence does not suggest that any "agent" that binds to this region or another region of the gonadotropin receptor would block, modulate, antagonize or agonize the receptor. Furthermore, the claims are drawn more specifically to a method of reducing the incidence of preqnancy in a female subject comprising administering to a female subject an amount of an agent effective at reducing the incidence of conception, wherein the agent inhibits CG activity or CG interaction with the exoloop 1, exoloop 2 or exoloop 3 domain of the LHR, wherein the agent is CG, a biologically active fragment thereof or other synthetic or natural compound. The evidence presented by Applicant does not provide enablement for a method of reducing the incidence of pregnancy.

The scope of the word "agent" and the phrase "other synthetic or natural compound" is not enabled by the disclosure. An agent that inhibits CG activity, wherein said agent is CG, a biologically active fragment thereof, or other synthetic or natural compound encompasses a vast breadth of possible agents, many of which are yet undiscovered. The claims reciting agents amount to single means claims. Single means claims are those that cover every conceivable means for achieving the stated purpose. Single means claims are nonenabling for the scope of the claim because the specification discloses at most only those means known to the inventor, in this case, CG. When claims depend on a recited property, a fact situation comparable to Hyatt is possible, where the claim covers every conceivable structure (means) for achieving the

stated property (result) while the specification discloses at most only those known to the inventor. See MPEP 2164.08(a).

The development of contraceptive methods comprising administration of "agents" or ""other synthetic or natural compound[s]" encompasses drug discovery and development, however, it also encompasses protein, gene therapy, nutriceuticals, and nearly anything under the sun one could administer to reduce the incidence of conception. Assuming a reasonable interpretation of the claims and that the Applicant meant a pharmaceutical agent, drug discovery is a labor intensive and expensive undertaking, in spite of recent developments in high throughput screening, rational drug design and combinatorial chemistry. According to Swartz and Babelnick, (cited in previous office action mailed 27 October 2005), research on and development of novel contraceptives has not kept pace with the growing need, and financial, legal and political pressures is a barrier to development of new contraceptive products in the United States (see p. 31, column 2, 2nd paragraph and p. 315, column 1, 2nd paragraph). Applicants contemplate possible agents that would inhibit CG interaction with exoloops 1, 2 or 3 of the LHR (polypeptides, nucleic acids, rDNA molecules for polypeptides) on pps. 25-33, and methods for ***identifying*** agents that modulate gonadotropin activity are contemplated on pps. 39-44 and assays for gonadotropin receptor binding are described in the references submitted by Applicant 8 May 2006, however, well known assays in the art for ***discovering*** agents are not equivalent to a positive recitation of how to make said agents. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention

commensurate in scope with these claims. ***Rather, the disclosure teaches how to discover such agents***. This is equivalent to presenting the public a method of discovering agents that have a certain effect, and then obtaining rights for them. These claims fail the "how to make" prong of 35 U.S.C. 112 first paragraph.

Due to the large quantity of experimentation necessary to determine which of the broadly claimed agents block CG activity, the lack of direction/guidance presented in the specification regarding how to make said agents and the absence of working examples directed to the same, the complex nature of the invention, and the breadth of the claims which fail to recite limitations on agents that block CG activity, undue experimentation would be required of the skilled artisan to make the claimed invention in its full scope.

The rejection of claims 16-17 under 35 U.S.C. 112, first paragraph, as set forth at pps 10-12 for failing to comply failing to comply with the written description requirement is maintained for reasons of record and the following. Applicants argue at p. 16, that simply identifying an appropriate fragment for inhibiting and affecting CG activity or CG interaction with the exoloop 1, exoloop 2 or exoloop 3 domain of the LHR would be within the purvue of the skilled artisan and is supported by what is known in the art and specification as filed. Applicants' arguments have been fully considered but are not found persuasive for the following reasons. The claims are directed to a method of contraception in a female subject comprising administering an agent, wherein the agent is defined in the claims by activity alone. However, there is no description of the agent itself in the specification, other than CG itself. The factors to be considered include

disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in claim 16 is a functional requirement and claim 17 is CG or a biologically active fragment thereof, or other synthetic or natural compound. Since this encompasses any structure that has the required activity, it does not define any structure. While a CG protein could be made, there is no recitation of what constitutes biologically active fragments or other synthetic or natural compounds. The specification teaches methods for ***identifying*** agents that modulate gonadotropin activity and assays for gonadotropin receptor binding are described in the references submitted by Applicant 8 May 2006, however, well known assays in the art for ***discovering*** agents are not equivalent to a positive recitation of how to make said agents. Applicants have claimed methods of contraception, but describe only methods of discovering agents that could be potentially useful as contraceptives—reach through method claims. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Claim Rejections - 35 USC § 102

The rejection of claim 16-17 under 35 U.S.C. 102(b), as set forth at p. 12 of the prior office action (mailed 27 October 2005) for being anticipated by Talwar et al. (cited in previous office action) is maintained for reasons of record and the following. Applicants' argue that Talwar et al. do not teach every element of the claims and that

Talwar et al. teach a pregnancy vaccine that is irreversible and would irrevocably sterilize a patient. Applicants' arguments have been fully considered but are not found. persuasive. Vaccines are not generally irreversible (see, for example, Munoz, Semin Pediatr Infect Dis. 2006; 17: 14-19, who teaches in the abstract that waning immunity after childhood immunization has resulted in a growing number of adults who are cable of contracting and transmitting pertussis), and Talwar et al. in particular teach a reversible vaccine (see abstract, "fertility was regained when titers fell..." and p. 8535, left column, last paragraph, "[t]iters for protection have...been defined. Since antibody titers decline spontaneously unless booster injections are given, ***the duration of effective immunization can be controlled by the woman herself***' emphasis added). Thus the argument that a vaccine would sterilize the patient is not persuasive.

Applicants' also argue at p. 17 that a vaccine using CG could attack the pituitary gland that expresses LH and FSH. This argument has been fully considered but is not persuasive. The issue is ***anticipation***; not a critical review of the teachings of Talwar et al., and Talwar et al. anticipate the claims in that they teach each and every element of the claimed methods, namely a method of reducing the incidence of pregnancy in a female subject comprising administering to a female subject an amount of an agent effective at reducing the incidence of conception, wherein the agent is CG, a biologically active fragment thereof or other synthetic or natural compound. Although the mechanism of action of hCG interaction with exoloop 3 of the LHR was not known to the authors, the discovery made by Applicant does not render an old composition or method patentable, see MPEP 2112: (I. Something which is old does not become patentable

upon the discovery of a new property). Second, Talwar et al. teach at p. 8532, left column, 1st paragraph that "[a]n advantage in choosing hCG as a target for immunocontraception is that its inactivation would not interfere with other physiological process in the female, such as ovulation and production of sex steroid hormones," thus the argument that the method taught by Talwar et al. is untenable is not persuasive. Finally, the claims recite no method step, dosage, route of adminsteration or anything else that distinguishes the claimed method over the method of Talwar.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christina Borgeest whose telephone number is 571-272-4482. The examiner can normally be reached on 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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ELIZABETH KEMMERER
PRIMARY EXAMINER